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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/519,044	09/02/2005	Robert Norman Barker	0380-P03549US0	6955

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EXAMINER	
JUEDES, AMY E	

ART UNIT	PAPER NUMBER
1644	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/519,044	BARKER ET AL.	
	Examiner	Art Unit	
	AMY E. JUEDES	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 January 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13 and 15-46* is/are pending in the application.

4a) Of the above claim(s) *3-5,8-13,15-40 and 44-46* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,6,7 and 41-43* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's amendment, filed 1/30/08, is acknowledged.

Claims 1-8, 16-25, 27-33, and 35-39 have been amended.
Claims 41-46 have been added.
Claims 1-13 and 15-46 are pending.

2. Applicant's election with traverse of group III, drawn to a method of tolerising a population of cells comprising administering a tolerogenic peptide to a subject, claims 1-2, 6-7, and 41-43, in the reply filed on 1/30/08 is acknowledged. Applicant has further elected SEQ ID NO: 4 as the species of peptide.

Applicant's traversal is on the grounds that the PCT Examiner did not make a lack of unity finding at the international stage of this Application. However, the findings of another agency at the international stage are not relevent to the prosecution of the instant U.S. application.

Applicant further argues that the restriction is improper, since Izumi et al. do not disclose a pharmaceutical composition, as recited in the instant claims, since the reference makes absolutely no disclosure about administering said composition to a subject. Group V is directed to a product, a composition comprising a target antigen in a pharmaceutically acceptable carrier. The limitation of a composition for "tolerisation of an individual" refers to an intended use of the claimed composition, and carries no patentable weight in the absence of a structural difference. Izumi et al. disclose a composition comprising mammalian cell cultures expressing an LMP1-flag fusion protein. Since cell culture medium is not incompatible with physiologic activity, said medium can be considered a pharmaceutically acceptable carrier. Thus, the composition comprising LMP1-flag is structurally identical to the "pharmaceutical" composition of the instant claims.

Applicant further argues that the Examiner has not adequately explained why there is no single general inventive concept, since no reasoning has been provided as to how the Izumi et al. reference provides justification for dividing the remainder of the claims up into 8 different groups. Unity of invention requires the claims to share a special technical feature that defines the contribution as a whole over the prior

art. Since the invention of group V lacks a special technical feature that defines the contribution over the prior art of Izumi et al., the claimed invention, considered as a whole, is not linked by a special technical feature and there is no single general inventive concept.

Applicant further argues that the entire claim set shares the common special technical feature of peptides that can be used to induce tolerance to a target antigen in an individual. However, as noted above, the intended use limitation of the product of group V does not carry any patentable weight, and thus the product of group V does not have a special technical feature that defines the contribution over the prior art of Izumi et al.

Applicant further argues that groups I-IV share a common special technical feature since they involve inducing tolerance, and relate to the same inventive concept. However, unity of invention requires the invention as a whole to share a special technical feature.

The requirement is still deemed proper and is therefore made FINAL.

Therefore, Claims 3-5, 8-13, 15-40, and 44-46 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claims 1-2, 6-7, and 41-43 read on the elected invention and are being acted upon.

3. The disclosure is objected to because it contains embedded hyperlinks and/or other form of browser-executable code on pg. 34. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP §608.01.

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-2, 6, and 41-43 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written

description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Specifically, there is insufficient written description to demonstrate that applicant was in possession of the claimed genus of tolerogenic peptide sequences "from EBV LMP1 or LMP2 protein".

The instant claims are drawn to a method of tolerising a cell comprising administering a tolerogenic peptide "from EBV LMP1 or LMP2 protein. The claims are not clearly limited to peptides from EBV encoded LMP1 or EBV encoded LMP2, but might reasonably encompass any peptide from "EBV" (i.e. from any type of EBV encoded protein such as EBV nuclear antigens, lytic antigens, etc.). Furthermore, the claims might encompass peptides from LMP1 or LMP2 proteins derived from other viruses. These peptides would all be structurally different since they are derived from structurally and functionally different proteins. In contrast to the broad range of structurally different peptides encompassed by the claims, the instant specification only discloses peptides derived from EBV encoded LMP1 and EBV encoded LMP2. Thus, one of skill in the art would conclude that the specification fails to provide adequate written description to demonstrate that Applicant was in possession of the claimed genus. See *Eli Lilly*, 119 F. 3d 1559, 43, USPQ2d 1398.

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 1-2, 6-7, and 41-43 are rejected under 35 U.S.C. 102(b) as being anticipated by Meij et al., 1999, as evidenced by Dukers et al., 2000 (of record).

Meij et al. teach immunizing mice with a 386 amino acid recombinant EBV encoded LMP1 protein (see page 1109 in particular). As evidenced by Dukers et al., said recombinant LMP1 protein comprises the sequence of SEQ ID NO: 4 of the instant application (see page 664 and Table I in particular, residues 16-35). Thus, the recombinant LMP1 protein of Meij et al. can be considered a fusion protein comprising the tolerogenic peptide SEQ ID NO: 4 (i.e. amino acids 16-35) linked to a "target antigen" (i.e. amino acids 36-386 of LMP1). Furthermore, since the mice produce antibodies to the EBV encoded-LMP1 protein, they can be considered "seropositive" for EBV. Additionally since Meij et al. have administered said LMP1 protein comprising a tolerogenic peptide and a target antigen directly to a subject, as recited in the instant claims, they must have inherently contacted antigen presenting cells and tolerised a cell population of the subject to the target antigen.

Thus, the reference clearly anticipates the invention.

7. Claims 1-2, 6-7, and 41-43 are rejected under 35 102(e) as being anticipated by WO 03/048337, as evidenced by Dukers et. al., 2000 (of record).

WO 03/048337 teaches administering EBV encoded LMP1 protein to a subject (see page 5 in particular). As evidenced by Dukers et al., said EBV encoded LMP1 protein comprises the sequence of SEQ ID NO: 4 of the instant application (see page 664 and Table I in particular, residues 16-35). WO 03/048337 also teaches that the LMP1 protein can be in the form of a fusion protein with an antigenic tag (i.e. a target antigen, see page 36 in particular). WO 03/048337 also teaches that the subject produces antibodies to the LMP1 protein, and thus the LMP1 protein is administered to a subject "seropositive" for EBV (see page 5 and 8 in particular). Additionally since WO 03/048337 teaches administering an LMP1 protein comprising the tolerogenic peptide of SEQ ID NO: 4 and a target antigen directly to a subject, as recited in the instant claims, they must have inherently contacted antigen presenting cells and tolerised a cell population of the subject to the target antigen.

Thus, the reference clearly anticipates the invention.

8. Claims 1-2, 6-7, and 41-43 are rejected under 35 102(e) as being anticipated by U.S. Patent 6,642,008, as evidenced by Dukers et. al., 2000 (of record).

The '008 patent teaches administering EBV encoded LMP1 protein to a subject seropositive for EBV (see column 7-8 and 15, in particular). As evidenced by Dukers et al., said EBV encoded LMP1 protein comprises the sequence of SEQ ID NO: 4 of the instant application (see page 664 and Table I in particular, residues 16-35). The '008 patent also teaches that the LMP1 protein can be in the form of a fusion protein with other proteins or EBV epitopes (i.e. target antigens, see column 15 and 22 in particular). Since the '008 patent teaches administering an LMP1 protein comprising the tolerogenic peptide of SEQ ID NO: 4 and a target antigen directly to a subject, as recited in the instant claims, they must have inherently contacted antigen presenting cells and tolerised a cell population of the subject to the target antigen.

Thus, the reference clearly anticipates the invention.

9. No claim is allowed.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy E. Juedes, Ph.D. whose telephone number is 571-272-4471. The examiner can normally be reached on 8am - 5pm, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eileen O'Hara can be reached on 571-272-0878. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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